

## **REMARKS**

Reconsideration of this application, as amended, is respectfully requested. The claims have been amended to more clearly reflect the invention; these amendments are made without prejudice or disclaimer. Claims 1-38 have been cancelled. New claims 39-87 have been added. With this amendment, claims 39-87 are pending in this application. These amendments do not add new matter and are supported by the originally filed specification. Consideration and entry of these amendments is respectfully requested. Applicants reserve the right to prosecute any amended, cancelled, or otherwise unclaimed subject matter in this or another application.

### **Restriction Requirement**

The Examiner stated that the Applicant's previously made arguments regarding the restriction requirement were persuasive and that "Group I and II will be examined in their entirety. Group II however will be considered non-elected." These statements appear to be contradictory; clarification is requested. It is understood that the restriction requirement as to original claim 38, directed to methods of preventing abuse, is final.

### **Rejection of claims 1-14 and 20-36 under 35 U.S.C. § 102(e) as anticipated by Breder et al. (US 2003/0157168)**

Claim 1-14 and 20-36 stand rejected under 35 U.S.C. 102(e) as being anticipated by Breder et al. (US 2003/0157168). Claims 1-14 and 20-36 have been cancelled; the rejection is therefore moot. Applicants do not believe the rejection of claims 1-14 and 20-36 was proper, and would be similarly improper if applied to new claims 39-87.

The Examiner alleged that Breder teaches:

Beads coated with an opioid agonist, and opioid antagonist in non-releasable form are disclosed at [164] and entail multiple subunits with releasable therapeutic with a coated (sequestered) antagonist in each....Subunits with either agonist or antagonist are set out at [213].

Applicants do not believe Breder discloses a single pharmaceutical unit (i.e., a bead) coated with both an agonist and an antagonist. As stated at paragraph [164] of Breder:

When a hydrophobic controlled release coating material is used to coat inert pharmaceutical beads such as nu pariel 18/20 beads, which are

already coated with an opioid agonist, a plurality of the resultant solid controlled release beads may thereafter be placed in a gelatin capsule with the opioid antagonist in a substantially non-releasable form.

At paragraph [213], Breder refers to:

...melt extruded material...prepared without the inclusion of the opioid agonist and/or opioid antagonist particles, which are added thereafter to the extrudate. Such formulations typically will have the drugs mixed together with the extruded matrix material, and then the mixture would be tableted to provide a slow release of the opioid agonist.

In each of the cited sections, Breder merely describes agonists and antagonists within separately formulated units that are ultimately combined into a single capsule or extrudate. In contrast, the instantly claimed compositions relate to particles containing both antagonist and agonist within the same subunit. And it has not been demonstrated that Breder teaches the use of a surfactant in a blocking agent. Applicants respectfully maintain that Breder does not disclose the instantly claimed formulations.

**Rejection of claims 1-14 and 20-36 under 35 U.S.C. § 102(b) as anticipated by Breder et al. (US 2003/0157168)**

Claim 1-14 and 20-36 stand rejected under 35 U.S.C. 102(b) as being anticipated by Breder et al. (US 2003/0157168). Claims 1-14 and 20-36 have been cancelled; the rejection as to these claims is therefore moot. Applicants do not believe this rejection is applicable to new claims 39-87.

In addition to the substantive deficiencies of Breder detailed above, it is not a proper 102(b) reference. As stated at MPEP § 706.02(a):

If the publication or issue date of the reference is more than 1 year prior to the effective filing date of the application ( MPEP § 706.02), the reference qualifies as prior art under 35 U.S.C. 102(b).

As also stated at MPEP § 706.02:

(D) If the application properly claims benefit under 35 U.S.C. 119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35 U.S.C. 112 by the provisional application.

The instant application properly claims priority to provisional Ser. No. 60/412,208 filed Sept. 22, 2002 which therefore serves as the effective filing date. Breder was not publicly available until August 21, 2003, which after the effective filing date of the instant application. Accordingly, a 102(b) rejection based on Breder of any claim arising from the instant application is improper.

**Rejection of claims 1-14 and 18-36 under 35 U.S.C. § 102(e) as anticipated by Oshlack et al. (US 2003/0064099)**

Claim 1-14 and 18-36 stand rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al. (US 2003/0064099). Claims 1-14 and 18-36 have been cancelled; the rejection as to these claims is therefore moot. Applicants do not believe the rejection of claims 1-14 and 20-36 was proper, and would be similarly improper if applied to new claims 39-87.

In the rejection of claims 1-14 and 20-36, the Examiner alleged:

Beads coated with an opioid agonist, and opioid antagonist in non-releasable form are disclosed at [0084] and entail multiple subunits with releasable therapeutic with a coated (sequestered) antagonist in each. Subunits with either agonist or antagonist are set out at this paragraph. A Hydrophilic core, with an aversive agent coating further coated with a hydrophobic agent is listed at [0086].

However, at paragraph [0084], Oshlack describes the use of a “hydrophobic material...to coat inert pharmaceutical beads...comprising an opioid analgesic” and that “one or more aversive agents may also be coated onto the beads comprising the opioid analgesic.” At paragraph [0086], Oshlack states:

Spheroids or beads coated with an opioid analgesic are prepared, e.g., by dissolving the opioid analgesic in water and then spraying the solution onto a substrate, for example, nu pariel 18/20 beads, using a Wuster insert. Thereafter, the one or more aversive agent is optionally added to the beads prior to coating.

The Examiner has not shown that Oshlack teaches the application of an aversive agent to a bead that is not already coated with an analgesic. Applicants do not believe Oshlack teaches a single pharmaceutical unit comprising an antagonist coated with a composition comprising an agonist. In addition, it has not been demonstrated that

Oshlack teaches the use of a surfactant in a blocking agent. Applicants respectfully maintain that Oshlack does not disclose the instantly claimed formulations.

**Rejection of claims 1-14 and 18-36 under 35 U.S.C. § 102(b) as anticipated by Oshlack et al. (US 2003/0064099)**

Claim 1-14 and 18-36 stand rejected under 35 U.S.C. 102(b) as being anticipated by Oshlack et al. (US 2003/0064099). Claims 1-14 and 18-36 have been cancelled; the rejection is therefore moot. Applicants do not believe this rejection is applicable to new claims 39-87.

In addition to the substantive deficiencies of Oshlack detailed above, it is not a proper 102(b) reference. As stated at MPEP § 706.02(a):

If the publication or issue date of the reference is more than 1 year prior to the effective filing date of the application ( MPEP § 706.02), the reference qualifies as prior art under 35 U.S.C. 102(b).

As also stated at MPEP § 706.02:

(D) If the application properly claims benefit under 35 U.S.C. 119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35 U.S.C. 112 by the provisional application.

The instant application properly claims priority to provisional Ser. No. 60/412,208 filed Sept. 22, 2002 which therefore serves as the effective filing date. Breder was not publicly available until April 3, 2003, which after the effective filing date of the instant application. Accordingly, a 102(b) rejection based on Oshlack of any claim arising from the instant application is improper.

**Rejection of claims 15-17 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Breder et al. (US 2003/0157168)**

Claim 15-17 and 38 stand rejected under 35 U.S.C. 103(a) as being anticipated by Breder et al. (US 2003/0157168). Applicants do not believe the rejection of claims 15-17 and 38 was proper, and would be similarly improper if applied to new claims 39-87.

In this rejection, the Examiner alleged that:

...Breder et al does suggest multiple coating formulations with respect to the discussion of the figures. As such, those of ordinary skill at the time of the invention would have found it well within their skill to apply any number of hydrophobic coatings and aversive agent layers including those of the instant claims with a reasonable expectation of discouraging opioid abuse. As such, the instant claims would have been obvious to one of ordinary skill in the pharmaceutical arts at the time of invention given the disclosure of Breder et al.

Applicants respectfully maintain that the Examiner has not established a *prima facie* case of obviousness.

In a proper obviousness rejection, the Examiner must provide “a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” MPEP § 706.02(j). The Federal Circuit has recently reiterated that “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” to avoid “the pitfalls of hindsight that belie a determination of obviousness”. Innogenetics, N.V. v. Abbott Laboratories, No. 2007-1145, -1161 (Federal Circuit; Jan. 17, 2008), *citing In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“To facilitate review, this analysis should be made explicit.”) *See also KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The mere fact that the prior art may be modified does not make the modification obvious unless the prior art suggests the desirability thereof. In re Lalu, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). The Examiner simply alleges that because a number of coatings and aversive agent layers were described by Breder, the subject matter of previously pending claims 15-17 and 38 was obvious. The Examiner provides no “rational underpinning” for his conclusions or evidence of the desirability by anyone skilled in the art to obtain the claimed subject matter.

The Examiner has not supported his conclusions as required by the MPEP, the Federal Circuit Court of Appeals, and the U.S. Supreme Court. The reasoning provided in the Office Action simply cannot serve as the basis for a proper obviousness rejection. Thus, Applicants respectfully maintain that the Examiner did not establish a *prima facie* case of obviousness of previously pending claims 15-17 and 38.

### CONCLUSIONS

Reconsideration of this application, as amended, is respectfully requested. The Examiner is encouraged to contact the undersigned if it is believed doing so would expedite prosecution.

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